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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,843	11/24/2003	David A. Schwartz	SOL.003.DIV1	5194

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,843	SCHWARTZ, DAVID A.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007 and 16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,35,38,49 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,35,38,49 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The Sequence Listing filed March 28, 2007 is approved.

2. The substitute specification filed March 28, 2007, and amendments to the specification filed March 28, 2007 (located at pages 7-22 of the response), have not been entered. The relationship between these two amendments is unknown. It is not clear, e.g., if the amendments to the specification are to be entered before the substitute specification is entered, if the amendments to the specification merely repeat the changes to be made in the substitute specification, or if the amendments to the specification are to be entered after entry of the substitute specification is entered. If Applicant will confine his responses to a single set of amendments to the specification (and to a single set of amendments to the claims - see the Office action mailed October 4, 2006, page 3, second paragraph), this issue will not arise. Further, the amendments to the specification do not contain any amendment markings, making it unclear what changes to the specification are intended by Applicant. Finally, the substitute specification will not be entered because it includes a complete set of the claims as originally filed. If the substitute specification is entered, then the application contains two differing sets of claims, i.e. the set of original claims included with the substitute specification, and the set of amended claims included with the response, and it is unclear as to which set of claim amendments is intended to be prosecuted by Applicant.

3. The amendment to claim 35, step (ii), contained in the response filed April 16, 2007, is in improper format under 37 CFR 1.121(c)(2) because it contains amendment markings from the amendments made to the claim in the paper filed August 9, 2006. The amendment to claim 52 contained in the response filed April 16, 2007 is in improper format under 37 CFR 1.121(c)(2) because the second occurrence of "a-bromoacetamido" has been deleted from the claim without

the amendment having been marked with strikethrough. The amendment format of any future amendments to the claims should be carefully checked to ensure compliance with the rules. Amendments after final rejection which are found not to be in compliance with 37 CFR 1.121 will not be entered.

4. The disclosure is objected to because of the following informalities: At page 4, line 27, "limited" is misspelled. At page 51, line 30, a SEQ ID NO needs to be inserted after the nucleotide sequence. See 37 CFR 1.821(d). Appropriate correction is required.

5. Claims 5, 6, 35, 38, 49, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a derivative thereof" at claim 5, line 3; claim 35, line 6; and claim 38, line 7; is indefinite because it is not clear what degree of structural and/or functional similarity is required to be present in a compound of formula II or Va and a second compound in order for the second compound to be considered a "derivative" of the compounds of formulas II or Va. For example, it is not clear if a derivative must still comprise a hydrazine group and/or an aliphatic divalent group. While Applicant's specification at page 9, line 26 - page 10, line 24, describes examples of derivatives (note Applicant's use of the word "includes" at page 9, line 26), an example is not a definition. The word "derivative" also does not have any art-accepted definition.

6. Claims 7, 35, 38 and 52 are objected to because of the following informalities: Claim 7 does not end with a period. At claim 35, last line, and claim 38, second-to-last line, "biomolecule" should be changed to "biological molecule" so as to be consistent with the terminology used in the preamble to each claim. At claim 52, line 2, the letters occurring before

"bromoacetyl" and "bromoacetamido" no longer appear to be the Greek letter α. Appropriate correction is required.

7. Claims 6 and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claim 6 recites that R can be a saturated or unsaturated carbocyclic moiety of 3 to 20 atoms. However, with respect to cyclic groups, the independent claim limits R to being an aliphatic divalent cycloalkene group. Accordingly, dependent claim 6 is at least in part broader in scope than the independent claim and is therefore an improper dependent claim. Independent claim 5 recites R^1 and R^2 groups which are saturated straight chains of 3 to 20 carbon atoms. However, in the formula recited in dependent claim 7, the two groups which correspond to R^1 and R^2 of the independent claim are methyl groups, and are not encompassed by the independent claim.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 5-7, 35, 38, 49, and 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the WO Patent Application 01/70685. See, e.g., claims 5-7, 32, 35, and 38 of the WO Patent Application '685. The WO Patent Application '685 is available as prior art against the instant claims because of the current lack of an acceptable claim for priority under 35 U.S.C. 120.

10. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 93/14779. The WO Patent Application '779 teaches a compound at page 22,

Example 5. In Example 6, the compound of Example 5 of the WO Patent Application '779 is reacted with an arginine derivative, which is a synthetic biological molecule, and the product is then conjugated to the amino group of a solid phase resin (which corresponds to Applicant's surface) in Example 7. The reaction product of the compound of Example 5 and the arginine derivative of the WO Patent Application '779 is deemed to be a derivative of Applicant's compound of formula II in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of the WO Patent Application '779 and Applicant's claimed compounds to shift the burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of the WO Patent Application '779.

11. Claims 5 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Whelihan (U.S. Patent No. 6,238,860). Whelihan teaches polypeptides which are synthesized with a Glu-Gly-Gly-Gly-Ser spacer sequence, modified with a hydrazide functionality, and then immobilized on an aldehyde-functional methacrylate resin support (which corresponds to Applicants' surface). See column 14, lines 12-52. The polypeptide-spacer-hydrazide reaction product of Whelihan is deemed to be a derivative of Applicant's compound of formula II and of Applicant's conjugate of formula Va in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of Whelihan and Applicant's claimed compounds to shift the burden to

Applicant to provide evidence that the claimed compounds are unobviously different than those of Whelihan.

12. Claims 5 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sivam et al (U.S. Patent No. 5,521,290). Sivam et al '290 teaches derivatizing a monoclonal antibody with sulfhydryl groups, reacting a hydrazide-containing bifunctional linker of formula I with the derivatized monoclonal antibody, and then reacting the monoclonal antibody hydrazide with ricin A which has been oxidized to form aldehyde groups on its oligosaccharide moieties (and which corresponds to Applicants' natural or synthetic biological molecule of claim 38, step (ii)). See column 5, lines 60-67, and column 18, lines 25-61. The reaction product of the derivatized monoclonal antibody and the bifunctional linker of Sivam et al '290 is deemed to be a derivative of Applicant's compound of formula II and of Applicant's conjugate of formula Va in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of Sivam et al '290 and Applicant's claimed compounds to shift the burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of Sivam et al '290.

13. Applicant's arguments filed March 28, 2007 and April 16, 2007 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, second paragraph, based upon Applicant's use of the term "derivative" is maintained. Applicant has not chosen to be his/her own lexicographer with respect to the term "derivative", because no definition of the term has been provided in the specification. As noted by the examiner in the rejection, Applicant's specification at page 9, line

26 through page 10, line 24, only provides examples of derivatives, and does not provide a definition of the term. An example does not constitute a definition. Applicant's argument indicate that the word "includes" has been removed in each place it occurred in this "definition". A quick glance of the proposed substitute specification filed March 28, 2007 (see, e.g., page 12, line 24, of the marked-up copy) shows that this is not true. Given the amendment format chosen by Applicant for the proposed substitute specification (strikethrough of an entire page-long paragraph and underlining of an entire page-long replacement paragraph), it is impossible, absent a word-by-word comparison of the two paragraphs, to determine whether any other or all of the occurrences of "includes" have been changed.

The examiner has reviewed both the previous version of claim 7 and the current version of claim 7, and can not find a period at the end of the claim. Because other periods present in other claims can be seen by the examiner, the examiner does not believe that absence of a period from the end of claim 7 is, e.g., a scanning error.

The objection to claims 6 and 7 under 37 CFR 1.75(c) is maintained. Minor changes to the terminology of claim 6, and to the dependency of claim 7, do not affect the problem that independent claim 5 has defined R, R^1, and R^2 so as not to permit certain of the substituents recited in dependent claims 6 and 7.

The rejection over the WO Patent Application 01/70685 is maintained in the absence of an acceptable claim for priority.

The anticipation rejection of claim 5 over the WO Patent Application 93/14779 is maintained. The examiner does not assert that the reference teaches a compound satisfying the requirements of formula II. However, claim 5 is not limited to compounds of formula II, but

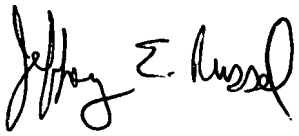
instead, as an alternative, also embraces derivatives of compounds of formula II. Aside from a conclusory statement that the proposed amended definition of "derivative" distinguishes over the reference, Applicant's argument does not contain any specific reasoning as to how the proposed amended definition of "derivative" distinguishes over the reference. The anticipation rejections over Whelihan (U.S. Patent No. 6,238,860) and over Sivam et al (U.S. Patent No. 5,521,290) are maintained for analogous reasons.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 17, 2007